HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
M2360n

Refer to: CFN 1122658

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4012

December 10, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Keith Cummings, Owner
Sweet 'n' Spicy Foods, Incorporated
2617 Windsor Avenue
Baltimore, Maryland 21216

Dear Mr. Cummings:

During an inspection of your firm conducted by the Food and Drug Administration (FDA) on November 19-23, 1998, numerous insanitary conditions were observed throughout the facility. For example:

1. Rodent-gnawed food (dried fish soup) was observed in the dry storage area.

2. A dead mouse was observed in the dry storage area.

3. The band saw used to cut beef, chicken, and fish was not cleaned and sanitized before cutting different products.

4. The cooler used to store perishables had a temperature of 50°F.

5. The hose and nozzle used to wash the cutting room, including food contact surfaces, was observed on the floor in standing water.

6. Droplets of an unidentified liquid were suspended on a condenser directly above raw, uncovered, whole fish in the freezer.

7. Food was stored directly on the floor in the freezer, cooler, and dry storage area.

Preparing, packing, or holding food under insanitary conditions renders the food adulterated under Section 402(a)(4) of the Food, Drug, and Cosmetic Act (Act), as the food may become contaminated with filth. Adulterated food is subject to seizure under the Act.

The aforementioned violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to insure that your facility is operated in a sanitary manner.

At the conclusion of the inspection, the FDA investigator presented to you a list of deficiencies (FDA-483). You should take prompt action to correct these violations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

During the inspection, the investigator evaluated your firm's compliance with FDA's seafood processing regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as a Hazard Analysis Critical Control Point (HACCP) plan. HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operations to eliminate or minimize the likelihood that the identified hazard will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have fully operating HACCP systems advise us that they benefit in several ways, including having a more safety-oriented workforce, less product waste, and generally, fewer problems.

During the inspection, the FDA investigator observed shortcomings in your system that, upon preliminary review, appear to be deviations from the principles of HACCP and the significant requirements of the program. The investigator provided you with a copy of the Domestic Seafood HACCP Report (Form FDA-3501) and a list of observations that presents his evaluation of your firm's performance regarding various aspects of HACCP. The observation of concern to us is as follows:

1. Your firm failed to establish and implement any HACCP plan for the fishery products you distribute.

We encourage you to make the necessary improvements as soon as possible. However, if you disagree with FDA's preliminary assessment of this deviation from the HACCP regulations, you should explain how your system identifies hazards and implements controls in a manner that the Agency will regard as complying with the regulations. We understand that HACCP systems may be uniquely tailored to meet the circumstances of the individual processor, and that there may be more than one right way to control hazards.

In either case, it is essential that you respond to this office on this matter. Upon receipt of a timely response, we will work with you to resolve any outstanding issues associated with your HACCP plan. Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to the Food and Drug Administration, Baltimore District Office, 900 Madison Avenue, Baltimore, Maryland 21201, attention: Wiley T. Williamson, III, Compliance Officer. If you have any questions regarding implementation of the HACCP regulations or the application of HACCP to your specific process, you may contact Mr. Williamson at (410) 962-4366, Extension 136.

Sincerely,

ELAINE KNOWLES COLE
District Director